JUN 1 5 2004

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3. **510(k) Summary:** K040701

Sponsor:
Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Sheri L. Musgnung

Device Name: Synthes (USA) Hydroxyapatite (HA) Coated Schanz Screws

Device Classification: 21 CFR 888.3040 – "Smooth or threaded metallic bone fixation fastener"

Predicate Device: Synthes Schanz Screws and Smith & Nephew Jet-X Half Pin.

Description of Device: Synthes HA Coated Schanz Screws are available as self-drilling and non-self-drilling designs. The HA Coated Schanz Screws are available in a variety of diameters and lengths. The threaded portion of the schanz screw is coated with a very thin plasma sprayed coating of HA.

Indications: Synthes HA Coated Schanz Screws are intended for use in an external fixation system for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Material: Titanium and stainless steel

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes HA Coated Schanz Screws is substantially equivalent* to other legally marketed devices.

* The term "substantially equivalent" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matter. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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4. **Device Name:**

Synthes (USA) Hydroxyapatite (HA) Coated Schanz Screws

5. **Establishment Registration:**

Synthes is registered with the Device Registration and Listing Branch of the U.S. Food and Drug Administration (FDA). The devices subject to this premarket notification are manufactured by Synthes (USA), 1101 Synthes Avenue, Monument, Colorado 80132, (FDA Registration No.: 1719045). The coating that is applied to this device is produced by Bio-Coat Inc., 21249 Bridge St. Southfield, Michigan 48034, (FDA Registration No.: 1833658).

6. **Classification Information:**

Synthes HA Coated Schanz Screws are classified as Class II, per the Code of Federal Regulations, Title 21, Section 888.3040: "Smooth or threaded metallic bone fixation fastener".

7. **Information Relating to Performance Standards and Special Controls:**

The materials used in the manufacturer of Synthes HA Coated Schanz Screws and the standards they adhere to are:

- Schanz Screws: CP Titanium (ASTM F67) and 316L Stainless Steel (ASTM F138)
- Coating: Hydroxyapatite (ASTM F1185)

The biological response to Hydroxyapatite in soft tissue and bone has been characterized by a history of clinical use and by laboratory studies. Attachment I of this premarket notification contains a letter to authorize FDA to reference Bio-Coat's Master Device File MAF-339 for information pertaining to Synthes HA coated schanz screws.

8. **Sterilization Information:**

Synthes HA Coated Schanz Screws will be provided sterile. See Attachment 2 for further information on sterile devices.

9. **Device Description:**

Synthes HA Coated Screws will be coated with a hydroxyapatite coating that is applied by Bio-Coat, Inc. The coating will be applied to the threaded portion of the Schanz screw by a plasma spray process. The coating thickness will be approximately 40 microns, with a total surface area ranging from 98mm^2 to 1590 mm^2. Please see Attachment 3 for a cross sectional view showing coating thickness and tolerances. Detailed product specifications related to the coating may be found in Attachment 4. Material characterization forms from Bio-Coat, Inc. MAF-339 (Titanium-Aluminum-Vanadium Alloy (TAV) and Commercially Pure Titanium (CP Ti) may be found in Attachment 5 and Attachment 6, respectively. For additional information on the material

characterizations, please see Synthes Engineering Rationale supported by the following Bio-Coat's Technical Reports in Attachment 7:

- Characterization of the Micrographic and Pore Morphological Characteristics of the Bio-Coat Hydroxylapatite Coating on Two Stainless Steel Bone Screws. (TR-54)
- Characterization of the Static Tensile, Static Shear and Shear Fatigue Properties of the Bio-Coat Hydroxylapatite Coating on Two Stainless Steel Bone Screws. (TR-55)
- Characterization of the Chemical and Crystallographic Characteristics of the Bio-Coat Hydroxylapatite Coating on 316 Stainless Steel. (TR-56)
- Characterization of the Static Tensile Strength, Static Shear Strength and Shear Fatigue Strength of the Bio-Coat HA Coating on CP Titanium. (TR-205)

Synthes HA Coated Schanz Screws feature either a self-drilling or self-tapping tip. They are available in sizes ranging from 2.5 mm to 6.0 mm in diameter and 60 mm to 250 mm in length. Please see Attachment 8 for Confidential Engineering Drawings.

10. Proposed Labels/Labeling:

Proposed labels and labeling can be found in Attachment 9.

11. Commercially Available Device Information:

The predicate devices, Synthes Self-Drilling Schanz Screws (K952296), Synthes 4.0/2.5 mm Self-Drilling Schanz Screws (K002605), and Smith & Nephew's Jet-X Half Pin (K023921), have been cleared for marketing via the premarket notification process. Synthes Schanz Screws have been commercially available since prior to May 28, 1976. Information on the predicate devices can be found in Attachment 10.

12. Comparison to Commercially Available Device:

A comparison of Synthes HA Coated Schanz Screws to the commercially available predicate devices follows in **Table 1.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

Sheri L. Musgnung
Synthes (USA)
1690 Russel Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K040701
Trade/Device Name: Synthes Hydroxyapatite (HA) Coated Schanz Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: II
Product Code: HWC
Dated: March 16, 2004
Received: March 17, 2004

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. **Indications for Use**

510(k) Number (if known): K040701

Device Name: Synthes Hydroxyapatite (HA) Coated Schanz Screws

Indications for Use: Synthes Hydroxyapatite (HA) Coated Schanz Screws are intended for use with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Miriam C. Provost
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number K040701